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| 10/824,527 | 04/15/2004 | Bum-Joon Kim | 5823.0260-00 | 7151 |
| 22852 | 7590 06/20/200 | 5 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | SITTON, JEHANNE SOUAYA | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | App | licant(s) | | | | |
|--|---|--|--|---|--|--|--|--|
| Office Action Summary | | 10/824,527 | кім | ET AL. | | | | |
| | | Examiner | Art | Unit | | | | |
| | | Jehanne S. Sittor | 1634 | 4 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHOWHIC - Externafter - If NO - Failu Any o | ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CF SIX (6) MONTHS from the mailing date of this communication of period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by steeply received by the Office later than three months after the need patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THIS CO R 1.136(a). In no event, howe n. eriod will apply and will expire statute, cause the application to | MMUNICATION. ver, may a reply be timely file SIX (6) MONTHS from the ma become ABANDONED (35 N | d illing date of this communication. U.S.C. § 133). | | | | |
| Status | | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 2 | 22 March 2006. | | | | | | |
| 2a) <u></u> □ | This action is FINAL . 2b)⊠ | s FINAL. 2b)⊠ This action is non-final. | | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | ion of Claims | | | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) 1-9 is/are pending in the application 4a) Of the above claim(s) 3 and 5-9 is/are version 5 claim(s) is/are allowed. Claim(s) 1,2 and 4 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and | withdrawn from consid | | | | | | |
| Applicati | ion Papers | | | | | | | |
| 10)🏻 | The specification is objected to by the Example The drawing(s) filed on 15 April 2004 is/are Applicant may not request that any objection to Replacement drawing sheet(s) including the control of The oath or declaration is objected to by the | e: a) accepted or b the drawing(s) be held prection is required if the | in abeyance. See 37 (e drawing(s) is objected | CFR 1.85(a). I to. See 37 CFR 1.121(d). | | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 2) Notice 3) Information | ot(s) Dee of References Cited (PTO-892) Dee of Draftsperson's Patent Drawing Review (PTO-948) Mation Disclosure Statement(s) (PTO-1449 or PTO/Sider No(s)/Mail Date 4/2004. | 3) B/08) 5) 🔲 | Interview Summary (PTO Paper No(s)/Mail Date Notice of Informal Patent Other: | • | | | | |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 1, 2 and 4, directed to SEO ID NO: 4 in the reply filed on 3/22/2006 is acknowledged. The traversal is on the ground(s) that the office has not explained why there would be a serious burden on the examiner if both groups I and II were examined together. This argument has been thoroughly reviewed but was not found persuasive as the previous restriction requirement stated "a search burden exists for searching more than one of the patentably distinct groups as art relating to the structural requirements of the product claims would not necessarily provide any information regarding methods of detecting bacteria and vice versa. Searching is therefore not coextensive". The response traverses the restriction requirement between SEQ ID NOS 3-61, and, while not addressing whether the nucleic acids are independent and distinct, notes that the MPEP requires examination of a reasonable number of sequences. This argument has been thoroughly reviewed but was not found persuasive as the search for group 1 requires a search of SEQ ID NOS: 1, 2, and 43 (elected sequence). The size of the databases required for search have grown exponentially over the past few years, such that the search burden for a single sequence has increased. Therefore, searching more than these three sequences represents a serious burden on the office. Accordingly, these three sequences are deemed to be a "reasonable number". Since the sequences of SEQ ID NOS 3-61 are distinct groEL2 gene fragments isolated from different strains of Streptomyces and are structurally distinct sequences and therefore patentably distinct, the requirement is still deemed proper and is therefore made FINAL.

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2. Claim 3 is withdrawn from consideration as it is drawn to non elected inventions.

Accordingly, a first action on the merits of group I, claims 1, 2, and 4 (directed to SEQ ID NO:

43), follows.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim recites a 'gene fragment', however the term is not limited to less than a full coding sequence but also encompasses genomic sequences as well as RNA which could exist in nature. The claims therefore do not distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non naturally occurring differences between the claimed products and naturally occurring ones. In the absence of the hand of man, the naturally occurring products are considered non statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor.

Claim Rejections - 35 USC § 112

Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a primer consisting of the sequence of SEQ ID NO: 1 or SEQ ID NO: 2, does not reasonably provide enablement for a primer which specifically amplifies groEL2 gene fragment of Streptomyces species comprising SEQ ID NO: 1 or SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue. These factors have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are drawn to a primer which comprises SEQ ID NO: 1 or 2 and specifically amplifies a groEL2 gene fragment from Streptomyces species. The specification does not define the term "specifically amplifies", however it is clear that the term encompasses primers which only amplify Streptomyces species as well as at least one Streptomyces species. Additionally, the specification contemplates "specific primer capable of amplifying groEL2 gene of all Streptomyces species". The claims therefore encompass primers which only amplify, that is are specific for, Streptomyces species, as well as primers which amplify groeL2 gene from all

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streptomyces species. Due to the use of the phrase "comprising", the claimed primers encompass sequences which may have any number of additional sequences on either side of SEQ ID NO: 1 and 2.

The specification teaches the sequence of SEQ ID NO: 1 and 2 and teaches that they were designed to amplify a groEL2 gene fragment from *S. lividans*, *S. albus*, and *T. paurometabola*, which is closely related to Streptomyces species (pages 18-19). The specification teaches that the primers were used to amplify a 420 bp fragment from 40 reference strains and 35 potato scab causing strains (page 22), and that comparison of the sequences in multi alignment showed interspecies variation. However, the specification does not teach if the amplified sequences represents groEL2 gene fragments from "all" Streptomyces species. While the specific sequences consisting of SEQ ID NOS: 1 and 2 may be capable of amplifying the groEL2 gene from Streptomyces species, it is not clear if such primers would be capable of amplifying "all" Streptomyces species groEL2 gene fragments. Further, even primers consisting of SEQ ID NO: 1 or 2 would not be capable of being "specific for" Streptomyces species. As exemplified from a sequence search for SEQ ID NOS 1 and 2, while each sequence has 100% identity to groEL2 sequences from Streptomyces, they are each also 100% identical to sequences from Mycobacterium, corynebacterium and bifobacterium.

SEQ ID NO: 1:

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SEQ ID NO: 2:

```
DEFINITION DNA fragment encoding a part of GroEL protein.
ACCESSION
          E10965
VERSION
          E10965.1 GI:22028829
SOURCE
          Corynebacterium glutamicum
          1 TGAAGGTGCCRCGGATCTTGTT 22 (SEQ ID NO: 2)
QУ
            748 TGAAGGTGCCACGGATCTTGTT 727
DEFINITION Bifidobacterium thermophilum heat shock protein 60 (hsp60) gene,
          partial cds.
ACCESSION AF240567
VERSION
          AF240567.1 GI:7243788
SOURCE
          Bifidobacterium thermophilum
          1 TGAAGGTGCCRCGGATCTTGTT 22 (SEQ ID 0: 2)
Qу
            557 TGAAGGTGCCGCGGATCTTGTT 536
Db
```

Accordingly, the sequences of SEQ ID NOS 1 and 2 do not appear to be capable of being specific for Streptomyces species.

With regard to the term "comprising", the specification does not teach or provide any guidance as to what additional sequences on either side of SEQ ID NO: 1 or 2 would be capable of being "specific for" Streptomyces species. The skilled artisan would be required to undertake a large amount of unpredictable trial and error experimentation to determine if any additional sequences on either side of SEQ ID NO: 1 and 2 would render the primers "specific for" Streptomyces species. The unpredictability is born out of the fact that the sequences appear to have a high degree of sequence identity from a diverse group of bacteria. Accordingly, the sequences would have to be tested with a large group of diverse bacteria at a number of different

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hybridization conditions, including conditions which vary in salt concentration, hybridization temperature, length of primer, GC content, etc. The specification, however, provides no guidance whatsoever as to what the identity of the additional nucleotides would have to be to achieve such specificity. Even excluding the recitation of the term "specifically" amplifies, the term "comprising" allows for a large amount of variability in the sequences on either side of the recited SEQ ID NOS. Again, other than demonstrating that the specific sequences consisting of SEQ ID NO: 1 or 2 are capable of amplifying sequences from Streptomyces species, the specification provides no guidance as to what sequences on either side of SEQ ID NO: 1 and 2 would be capable of amplifying groEL2 gene fragments from Streptomyces species. The addition of sequences on either side of SEQ ID NO: 1 or 2 would change the hybridization properties of the primer, allowing for cross-hybridization or non specific hybridization.

Accordingly, the scope of the claims is not commensurate in scope with the guidance in the specification and the skilled artisan would be required to perform undue experimentation to make and use primers as broadly claimed.

Written Description

7. Claims 1, 2, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1 and 2 are drawn to a primer which comprises SEQ ID NO: 1 or 2 and specifically amplifies a groEL2 gene fragment from Streptomyces species. The specification does not define the term "specifically amplifies", however it is clear that the term encompasses primers which only amplify Streptomyces species as well as at least one Streptomyces species. Additionally, the specification contemplates "specific primer capable of amplifying groEL2 gene of all Streptomyces species". The claims therefore encompass primers which only amplify, that is are specific for, Streptomyces species, as well as primers which amplify groeL2 gene from all streptomyces species. Due to the use of the phrase "comprising", the claimed primers encompass sequences which may have any number of additional sequences on either side of SEQ ID NO: 1 and 2. The claims therefore encompass a large variable genus of nucleic acid sequences. However, the specification only teaches the sequence of SEQ ID NO: 1 and 2.

The specification teaches that SEQ ID NOS: 1 and 2 were designed to amplify a groEL2 gene fragment from *S. lividans*, *S. albus*, and *T. paurometabola*, which is closely related to Streptomyces species (pages 18-19). The specification teaches that the primers were used to amplify a 420 bp fragment from 40 reference strains and 35 potato scab causing strains (page 22), and that comparison of the sequences in multi alignment showed interspecies variation. However, the specification does not teach if the amplified sequences represents groEL2 gene fragments from "all" Streptomyces species. While the specific sequences consisting of SEQ ID NOS: 1 and 2 may be capable of amplifying the groEL2 gene from Streptomyces species, it is not clear if such primers would be capable of amplifying "all" Streptomyces species groEL2 gene fragments. Further, even primers consisting of SEQ ID NO: 1 or 2 would not be capable of being "specific for" Streptomyces species. As exemplified from a sequence search for SEQ ID

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NOS 1 and 2, while each sequence has 100% identity to groEL2 sequences from Streptomyces, they are each also 100% identical to sequences from Mycobacterium, corynebacterium and bifobacterium.

SEQ ID NO: 1:

Db

```
DEFINITION Mycobacterium ulcerans putative 65 kDa heat shock protein (groEL)
           gene, partial cds.
VERSION
           AF271096.1 GI:11139537
Qу
           1 CCATCGCCAAGGAGATCGAGCT 22 (SEQ ID NO: 1)
             1111111111111111111111
Db
           2 CCATCGCCAAGGAGATCGAGCT 23
SEQ ID NO: 2:
DEFINITION DNA fragment encoding a part of GroEL protein.
ACCESSION E10965
VERSION
         E10965.1 GI:22028829
SOURCE
           Corynebacterium glutamicum
           1 TGAAGGTGCCRCGGATCTTGTT 22 (SEQ ID NO: 2)
Qу
             Db
         748 TGAAGGTGCCACGGATCTTGTT 727
DEFINITION Bifidobacterium thermophilum heat shock protein 60 (hsp60) gene,
           partial cds.
ACCESSION AF240567
VERSION AF240567.1 GI:7243788
SOURCE
           Bifidobacterium thermophilum
Qу
           1 TGAAGGTGCCRCGGATCTTGTT 22 (SEQ ID 0: 2)
```

Accordingly, the sequences of SEQ ID NOS 1 and 2 do not appear to be capable of being specific for Streptomyces species. With regard to the term "comprising" and the large variable genus encompassed by the claims, the specification does not describe or provide any guidance as

557 TGAAGGTGCCGCGGATCTTGTT 536

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to what additional sequences on either side of SEQ ID NO: 1 or 2 would be capable of being "specific for" Streptomyces species. The specification provides no guidance whatsoever as to what the identity of additional nucleotides would have to be to achieve such specificity. Even excluding the recitation of the term "specifically", the term "comprising" allows for a large amount of variability in the sequences on either side of the recited SEQ ID NOs. Again, other than demonstrating that the specific sequences consisting of SEQ ID NO: 1 or 2 are capable of amplifying sequences from Streptomyces species, the specification provides no guidance as to what sequences on either side of SEQ ID NO: 1 and 2 would be capable of amplifying groEL2 gene fragments from Streptomyces species. The addition of sequences on either side of SEQ ID NO: 1 or 2 would change the hybridization properties of the primer, allowing for cross-hybridization or non specific hybridization. Accordingly, the claims encompass a broad genus of possible nucleic acids, for which, the sequence of SEQ ID NO: 1 and 2 are not representative.

Claim 4 is drawn to nucleic acid sequences which comprise SEQ ID NO: 43.

Accordingly, the claim encompasses a genus of nucleic acids which can contain any number of sequences on either side of SEQ ID NO: 43. The specification teaches that SEQ ID NO: 43 a 420 base pair fragment of the groEL2 gene from a strain of Streptomyces, which is less than a full length coding sequence. Although the claim recites "derived from a potato scab microorganism", the specification does not provide any guidance as to the identity of the sequences on either side of SEQ ID NO: 43 which would identify it as "from a potato scab microorganism". Additionally, the term "derived" appears to indicate that the sequences could also be changed in some way so as to be considered "derived" from an original sequence.

Therefore, the partial gene sequence of SEQ ID NO: 43 is not representative of the genus of

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sequences encompassed by the claims, such as full length coding sequences, as well as sequences "derived" from potato scab microorganisms.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acids consisting of SEQ ID NOS: 1, 2, or 43, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

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obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Indefinite

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in the recitation of "a groEL2 gene fragment or fragment thereof". The double use of the term "fragment" makes it unclear if the claim encompasses a nucleic acid which comprising SEQ ID NO: 43, or a fragment of SEQ ID NO: 43, or both. Additionally, the use of the term "chosen from" does not conform with Markush language. The claim was amended from proper Markush format "selected from the group consisting of" to the instantly recited claim. The use of the term "chosen from" is indefinite because it is unclear if the sequences are "chosen" from the group of SEQ ID NO: 43-61, or also include sequences from within the recited SEQ ID NOS.

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Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Leckie (Leckie et al; US Patent 5,631,130; 1997).

Leckie teaches the sequence of SEQ ID NO: 54, which is 48 nucleotides long. Instantly claimed SEQ ID NO: 1 is completely identical to the complement of SEQ ID NO: 54 of Leckie at positions 8-29. The complement of SEQ ID NO: 54 is considered inherent in the disclosure of Leckie.

An alignment of SEQ ID NO: 54 with Genbank Accession number X95971 (which is Streptomyces albus groEL2 gene) is provided below.

GGTGTCCATCGCCAAGGAGATCGAGCTGGAGGATCCGTACGAGAAG (SEQ ID NO: 54)

* * *

GGTGTCTCCATCGCCAAGGAGATCGAGCTCGAGGACCCGTACGAGAAG (Genbank AC # X95971)

Given the degree of alignment, the sequence of Leckie would be capable of amplifying a groEL2 gene fragment from Streptomyces species under certain conditions.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tokunaga (Tokunaga et al; Microbiology and Immunology (1992), 36(1), 55-66).

Tokunaga teaches a 45 bp nucleotide sequence. An alignment of the sequence with Genbank Accession number X95971 (which is Streptomyces albus groEL2 gene) follows:

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Given the degree of alignment, the sequence of Tokunaga would be capable of amplifying a groEL2 gene fragment from Streptomyces species under certain conditions.

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13. Claim 4 is rejected under 35 USC 102(b) as being anticipated by Brennan (US Patent 5,474,796).

Brennan teaches an array comprising all possible 10 mer nucleic acid sequences (see cols 9-10). Claim 4 encompasses a genus of fragments of SEQ ID NO: 43. Accordingly, the fragments taught by Brennan anticipate the fragments encompassed by claim 4.

Conclusion

- 14. No claims are allowed
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Gehause Si Han Jehanne Sitton Primary Examiner

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